Corneal Refractive Surgery Surveillance Program (CRSSP)

Purpose: The CRSSP is intended to provide surveillance of the visual performance of Army aviation personnel who have had refractive surgery. Army Aviation is a highly visually demanding profession. Refractive surgery may in some cases change an individual's ability to see under low light or low contrast conditions. These parameters of vision are not tested in the standard FDME. This surveillance program seeks to evaluate the capabilities of aviation personnel to see under more rigorous visual conditions, to monitor changes in vision over time and to advise the Surgeon General on issues related to vision in the aviation environment.

Scope: The CRSSP is governed by the APL on Corneal Refractive Surgery and will be applied to personnel designated by the APL.

Responsibilities:

Flight Surgeons: Flight Surgeons initiate requests for entry into the CRSSP (see procedures below). Flight Surgeons ensure aviation personnel who have a waiver under the Corneal Refractive Surgery APL complete all required evaluations during the course of their career.

US Army Aeromedical Activity (USAAMA): USAAMA provides oversight of the CRSSP to include management of waiver and exception to policy requests, data management and coordination with aviation personnel for completion of required testing to maintain waiver status.

US Army Aeromedical Research Laboratory (USAARL): USAARL reviews applications for entry into CRSSP and provides recommendations to USAAMA for or against waiver or exception to policy. USAARL administers the visual performance battery to applicable categories of personnel, as described below. USAARL provides USAAMA with the data obtained for entry into the AEDR.

Procedures:

Aviator training applicants (Class 1W/1A): Aviator training applicants will enter the CRSSP in accordance with procedures already established in the USAARL study "Evaluation of Refractive Surgery for Army Aviation." In general, the time line is as follows: Three months post-operative the applicant provides surgical information (see Appendix 1) and flight physical to USAARL for review. USAARL recommends for or against exception to policy and submits recommendation to USAAMA. USAAMA recommends for or against exception to policy and submits to waiver authority. Applicant starts flight school and completes the study-specific visual performance battery that includes the tests listed below at four intervals: (1) at initial entry to finalize exception to policy, (2) at 3 months, (3) at 6 months and (4) at completion of flight school. Data from the visual performance test battery is provided to USAAMA for entry into the Aviation Epidemiological Data Register (AEDR).

Trained aviation personnel (Classes 2, 2F, 3, and 4): As specified in the APL, trained aviation personnel will enter the CRSSP by submitting surgical outcome information through their Flight Surgeon to USAARL (see Appendix 1). The refractive surgeon will determine when the applicant's eyes have stabilized adequately for possible return to flight duty. Surgical outcome information will not be accepted any earlier than 6 weeks post-operative. The following tests will be completed:

1. Manifest refraction (at least 2 refractions one week apart to establish stability)
2. Visual acuity (best corrected 20/20 each eye)
3. Slit lamp examination (no residual haze or other complications)
4. Corneal topography (post-operative topography map)
5. Contrast Sensitivity (5% contrast using the Precision Vision backlit chart)

USAARL reviews the information provided and forwards to USAAMA for entry into the AEDR and with a recommendation for or against waiver. USAAMA will review and inform the applicant's Flight Surgeon of required actions.

New accessions to Flight Surgeon/Aeromedical Physician Assistant (Class 2F), Nonrated Aircrew (Class 3), or ATC (Class 4): New accessions will submit surgical information through their Flight Surgeon to USAARL (see Appendix 1), and if accepted into the surveillance program, will complete the full visual performance battery at USAARL (see Appendix 2). The Flight Surgeon will arrange for the applicant to complete final testing at USAARL if the initial information provided indicates an adequate outcome after the surgery. USAARL will complete the visual performance test battery on waiver applicants and provide a recommendation for or against waiver to USAAMA. The data obtained will be provided to USAAMA for entry into the AEDR.

Waiver: If a waiver is granted, aviation personnel will be required to follow-up annually with their eye care provider (optometrist or ophthalmologist) to complete vision testing as specified in the APL. Follow-up examinations at USAARL will be completed at 3 to 5 year intervals during the course of the individual's career. These follow-ups will be completed on a voluntary basis, depending on each individual's assignment or schooling opportunities that require a period of time spent at Ft. Rucker.

Appendix 1 (Initial Application Information)

Request for Release of Medical Records
(completed by applicant and provided to eye care provider for completion)

From: (enter your information) Date:

To: (enter eye clinic information)

Subject: Request for records related to refractive surgery procedure

1. I am considering participation in a research study of refractive surgery in the military. Request a copy of records pertaining to my refractive surgery be provided to:

LTC Corina van de Pol, O.D., Ph.D.
US Army Aeromedical Research Laboratory (Visual Science Branch)
PO Box 620577
Ft. Rucker, AL 36362

Tel: 334-255-6876
FAX: 334-255-6993

2. The following information is needed:

Date of procedure
Type of procedure (PRK or LASIK)
Type of laser (brand name)
Ablation parameters (size of ablation zone, microns of tissue removed, number of pulses, if available)
Amount of correction (sphere, cylinder and axis)
Pre-operative refraction and date (specify manifest or cycloplegic)
Follow-up refractions with visual acuities and dates (most current refraction and as many postoperative refractions as possible)
Slitlamp assessment of cornea (presence or absence of haze or other complications)
Latest **post-operative** corneal topography (instantaneous or tangential corneal maps)
Contrast Sensitivity (preferred test is the 5% low contrast letter acuity)

3. Please contact Dr. van de Pol if you have any questions.

_____ _____
Typed or Printed Name of Applicant Signature of Applicant

Study applicant
Last name: _____ First name:_____ Middle initial:____

Date of Birth: _____ Contact Tel. #: _____

Eye Care Provider
Name: _____ Date of report: _____

Clinic address & telephone: _____
_____

Specific procedure details

Date of Procedure: _____ Type *(circle one)*: PRK or LASIK
Laser Used: (manufacturer)_____ (model #) _____

Ablation parameters (Complete below, or if available, attach copies of laser records)
OD: Size of ablation: _____ *mm* Tissue removed: _____ *microns* # of Pulses: _____
OS: Size of ablation: _____ *mm* Tissue removed: _____ *microns* # of Pulses: _____

Amount of correction programmed into laser
OD: _____ OS:_____

Pre-operative Refraction
OD:_____ OS:_____

Did the applicant require any enhancement procedures? Yes _____ No _____
(If yes, please provide details, as above)

Follow-up examinations (include most recent and 2 prior examinations)

Date	Refraction	Visual acuity	Corneal haze* (circle one)
	OD_____ OS _____	OD_____ OS_____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD_____ OS _____	OD_____ OS_____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD_____ OS _____	OD_____ OS_____	OD 0 1 2 3 4 OS 0 1 2 3 4

*** Haze 0-4 scale**. 0=no haze, 1=trace, 2=minimal, 3=moderate, 4=iris details obscured.

Corneal topography (include copy of most recent corneal topography using the TANGENTIAL or INSTANTANEOUS map display option)

Topographer used: _____
Manufacturer: _____
Model: _____
Date of topographies: _____

Contrast sensitivity (attach copy of results, if available)

Test Used:
Manufacturer: _____
Model: _____

Date of contrast test: _____

Test Conditions:
Room Lights ON (circle one) Yes No
Backlit Chart (circle one) Yes No
Distance to test _____m
% Contrast (if letters) _____%

Results:
OD _____
OS _____

Thank you for completing the information. Please return this form and supporting records to:

LTC Corina van de Pol, O.D., Ph.D.,
US Army Aeromedical Research Laboratory
Bldg 6901, PO Box 620577
Ft. Rucker, AL 36362

Tel: (334) 255-6876
Fax: (334) 255-6993

Appendix 2 (USAARL Visual Performance Test Battery)

Only designated personnel will complete the full test battery. The USAARL battery includes measures of refractive error, corneal shape, pupil size, high contrast visual acuity, low contrast visual acuity, contrast sensitivity, low luminance testing and glare disability (see table).

Table
CRSSP Performance Measures & Norms (USAARL Visual Performance Battery)

Ocular parameters	**Test**
Refractive Error	Manifest refraction using a phoropter and visual acuity chart at 6 meters
Pupil Size under photopic and mesopic conditions	Colvard Pupillometer with standard and low ambient light levels
Corneal shape	Orbscan Topography measures anterior and posterior corneal shape and corneal thickness
Visual performance measure	**Test (norm 2 standard deviations)**
High contrast visual acuity (HCVA)	ETDRS logMAR chart at 4 meters (-0.11 0.15 logMAR; 20/16)
Low contrast visual acuity (LCVA)	ETDRS logMAR 5% low contrast chart or Precision Vision small 5% chart at 4 meters (0.28 0.20 logMAR; 20/40)
Contrast sensitivity (CS)	Rabin Small Letter Contrast Test (front lit 100 cd/m^2) at 4 meters (1.00 0.25 logCS)
Mesopic contrast sensitivity (MCS)	SLCT (front lit 3 cd/m^2) under low luminance conditions at 4 meters (0.50 0.35 logCS)
Glare disability (GD)	Berkeley Glare Test at 1 meter (10 3 letters)

The following section describes each test:

Manifest Refraction: Refractive error will be measured using standard clinical techniques for manifest refraction. This involves use of an eyelane with a phoropter and a projected visual acuity chart. The acuity measured using the projected chart will only be used for determination of the endpoint of the refraction. HCVA for purposes of the study will be measured as noted below. The manifest refraction in terms of sphere power, cylinder power and axis will be provided for entry into the AEDR.

Pupil Size: Pupil size will be measured using the Colvard Pupillometer with the ambient room lighting set at the same levels used for the contrast sensitivity and mesopic visual tests described above. Pupil size, in millimeters, will be provided for the low and standard lighting conditions for entry into the AEDR.

Corneal Topography: Corneal shape will be measured using the Orbscan Topography unit. This unit provides information about the anterior and posterior surface curvature and corneal thickness over a 6 to 8 millimeter diameter region of the cornea. The tangential power map of the anterior surface of the cornea will be printed out and provided to USAAMA for archive.

High Contrast Visual Acuity (HCVA): Visual acuity is the standard measure of visual capability used in clinical settings. HCVA charts consist of black letters of decreasing size on a white background and are designed to determine the minimum angle of resolution that an eye can see. Normal vision is defined as the ability to resolve at least one minute of arc detail or 20/20 visual acuity. Most individuals under the age of 60 are able to resolve better than one minute of arc, often achieving 20/15 or 20/10 vision. HCVA will be measured at distance using the ETDRS (charts developed for the Early Treatment of Diabetic Retinopathy Study) high contrast visual acuity chart at 4 meters. The back-lit ETDRS chart uses a standardized logarithmic progression of letter sizes to ensure equal visual demand at threshold. Visual acuity will be recorded in logMAR and converted to 20/20 equivalency for entry into AEDR.

Low Contrast Visual Acuity (LCVA): The ability to see low contrast letters is affected by the presence of ocular opacities or significant aberrations. LCVA charts are most commonly used in the diagnosis and management of cataracts, since HCVA can often be normal long after patients report visual symptoms. If corneal refractive surgery results in corneal opacities such as haze or aberrations due to decentered or irregular ablations, LCVA is expected to be affected even when HCVA is normal. LCVA will be measured using the back-lit ETDRS low contrast visual acuity chart or the smaller Precision Vision chart, both of which have a contrast level of 5%. LCVA will be recorded in logMAR and converted to 20/20 equivalency for entry into the AEDR.

Contrast Sensitivity (CS): The Small Letter Contrast Test (SLCT) was developed at USAARL in response to the need for a more sensitive measure of the visual capabilities of U.S. Army aviator candidates. This group is generally young, often emmetropic, with excellent HCVA. Low visibility and low luminance are two significant conditions that have been found to differentially affect individual pilot performance. How well an individual sees under these circumstances often determines his or her success as a pilot. It is anticipated that the effect of changes in corneal optics and clarity after refractive surgery will be more detectable with the SLCT than HCVA. While LCVA measures performance at a specific contrast level, the SLCT measures performance at one spatial frequency across a range of contrast levels (see Figure 3). CS will be measured using the SLCT set at 4 meters so that the letters subtend 1.25 minutes of arc or 20/25, near the visual acuity threshold. CS will be recorded in logCS and reported to USAAMA as such for entry into the AEDR.

Mesopic Contrast Sensitivity (MCS): The SLCT will be used to assess contrast sensitivity under low luminance conditions. The room lights will be set such that the chart luminance is 3 cd/m^2 and the chart will be set 4 meters from the subject. Patients will be allowed to adapt to the lower light level before measurements are made. MCS will be recorded in logCS and reported to USAAMA as such for entry into the AEDR.

Glare Disability (GD): The Berkeley Glare Test (BGT) uses a low contrast chart with 10% contrast letters of decreasing size using logarithmic progression and scored in terms of letters missed. The chart is mounted on a plexiglass surface in a unit that has internal lighting to provide a glare source around the chart. Low contrast visual acuity is measured without the glare source on and then with the glare source. Glare disability is defined as the decrease in low contrast visual acuity between the non-glare and glare settings of the device and is recorded in terms of difference in number of letters missed between the two conditions. The number of letters missed will be entered into the AEDR.